No. 89-770

IN THE

Supreme Court of the United States

OCTOBER TERM, 1989

SMEC, INC.,

Petitioner,

v.

DATASCOPE CORP.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF RESPONDENT, DATASCOPE CORP., IN OPPOSITION TO PETITION

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COUNTER-STATEMENT OF QUESTIONS PRESENTED FOR REVIEW

1. Did the court of appeals properly discharge its appellate review function by first holding certain inferences drawn and certain findings made by the district court to be clearly erroneous and then entering judgment based upon those of the district court's findings which were held not to be clearly erroneous?

2. Did the court of appeals properly enter judgment, without remanding to the district court, when the record and the undisturbed findings of the district court indicated that any other judgment would be clearly erroneous?

3. When the court of appeals, in the alternative, vacated certain findings and inferences as a matter of law, was it proper for it to enter judgment on the district court's undisturbed findings, when that judgment is, on the record and as a matter of law, the only one that could be sustained?

PARTIES

The identification of parties in petitioner's brief incorrectly identifies respondent. Respondent herein is Datascope Corp. (hereinafter "Datascope"). Datascope has no parent companies, subsidiaries (other than wholly owned subsidiaries) or affiliates.

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Datascope Corp. respectfully requests that the SMEC, Inc. Petition for a Writ of Certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit be denied.

OPINIONS BELOW

The petition herein of SMEC, Inc. (hereinafter "SMEC") is from the decision of the Court of Appeals for the Federal Circuit on the damage phase of the subject litigation. That decision of the court of appeals, as well as the decision of the district court on the damages trial are reprinted in the Appendix to petitioner's brief. What cannot be found in petitioner's Appendix is the decision of the district court (reported at 594 F.Supp. 1306 (D.N.J. 1984)) on the liability phase of this case. Since that decision is believed to be relevant to putting the issues raised by the instant petition in context, it is reprinted in the Appendix to this brief at pages App. 1 - App. 17. For an understanding and appreciation of the nature and significance of the invention covered by the patent here at issue, this Court is referred to and respectfully urged to read that opinion.

COUNTER-STATEMENT OF THE CASE

The complaint in this case was filed in December 1981. After substantial discovery and considerable motion practice, a bench trial was had during the first half of 1984, with final argument having been held in August of that year. The decision, rendered September 24, 1984, holding Datascope's U.S. patent No. 4,261,339 (hereinafter "the '339 patent") valid and infringed[1] was appealed, and the affirmance on appeal issued on November 1, 1985. Thereafter, and despite Datascope's persistent efforts to move the case along, the damage trial was not held until May and June of 1987, with the decision being rendered on January 19, 1988. The appeal from that damage trial decision was rendered on July 6, 1989. It is the judgment entered on this July 6, 1989 decision to which the instant petition is directed.

[1] A second patent, no longer involved in this case, was held to be invalid.

SUMMARY OF ARGUMENT

The court of appeals did not substitute its own findings of fact for those of the district court. Indeed, it made no new findings at all. Rather, while it held certain of the inferences drawn and some of the findings of fact made by the district court to be clearly erroneous, most of the district court's findings were left undisturbed. The court of appeals then entered judgment based upon the latter. It did not enter judgment upon findings it made *de novo*.

Moreover, even if the court of appeals had made its own findings and entered judgment thereon, that would not have been improper. When a court of appeals decides that the facts of record will support only one finding or one inference, *i.e.*, when it determines that any other finding or inference would necessarily be clearly erroneous, it may enter judgment on that finding without the need to remand.

ARGUMENT

INTRODUCTION

According to petitioner, the court of appeals, in reversing, went beyond determining that the district court's findings were clearly erroneous — it impermissibly substituted its own findings for those of the district court (P. 6, 8).[2] Of course, that is not at all what the court did.

To accept petitioner's argument, one must find that the court of appeals either was ignorant of the provisions of Rule 52(a), chose to ignore those provisions or simply did not realize what it was doing. We submit that to sustain such a serious indictment, a petitioner must show far more, by several orders of magnitude, than has been shown in this case.

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[2] "P." followed by a page number will be used herein to identify references to the Petition For Writ of Certiorari.

That the court of appeals recognized and understood the limited nature of its appellate review authority is clear. At the outset, it said "[w]e review asserted factual errors cognizant of the clearly erroneous standard of Fed. R. Civ. P. 52(a)" (P. 6a). It then explained in considerable detail why it was forced to conclude, based upon the law, the unchallenged facts of record, and the district court's own findings, that the several findings and inferences which were reversed were clearly erroneous. It did not set aside findings simply because, if it had been conducting a *de novo* review, it might have found otherwise. Indeed, it expressly recognized that such is not the province of an appellate court. In discussing reasonable royalty, the court said "[w]ere we sitting *de novo* we might also have found a higher rate reasonable. The role of an appellate court is not, however, to substitute its judgment for that of the district court." (P. 13a).

Despite having been castigated by the court of appeals for adopting "the frequent and foolish appellate ploy of citing only such bits of evidence as may support its view, while ignoring the wealth of evidence. . . ." (P. 8a) on the other side, petitioner persists here in following that same pattern. When one takes into account *all* the findings of the district court, then discards those which were found to be clearly erroneous, it becomes quite evident that the judgment entered by the court of appeals was not based upon its own *de novo* findings, but, instead, was based upon those findings of the district court which were not overturned.

THE COURT OF APPEALS ADOPTED THE FINDINGS OF THE DISTRICT COURT

1. *Lost Profits*

In accusing the court of appeals of having ignored Rule 52(a), petitioner grossly misstates the findings of the district court. Thus, petitioner asserts that

> [t]he District Court simply found that the SMEC customers would have stayed with the proven surgical design until a SMEC percutaneous balloon was on the market and would not have purchased the Datascope percutaneous balloon "but for" the SMEC infringement. . . ." (P. 13-14).

To the contrary, the district court found (P. 23a)

> that *regardless of the doctors' high regard for Schiff and SMEC*, these doctors would have adopted the percutaneous method .... (emphasis supplied).

Indeed, the court of appeals pointed specifically to and, in fact, even quoted this very finding (P. 10a).

The reason why these customers would have purchased non-SMEC percutaneous IABs "regardless of [their] high regard for Schiff and SMEC . . ." is also found in the unchallenged findings of the district court.

> Percutaneous balloons did, however, offer a number of benefits over surgical balloons. Prior to the introduction of the percutaneous technology, surgical balloons were the catheter of choice among doctors. Among the advantages of percutaneous insertion are that it requires use of local anaesthesia to a lesser extent than does the surgical method; a percutaneous balloon can be inserted more quickly and easily into the patient; and it avoids a painful incision while the patient is under local anaesthesia.[3] (P. 23a).

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[3] Other advantages can be found described in the district court's liability decision (App).

It was inevitable, therefore, according to the district court, that the switch would have been made irrespective of SMEC's presence in the market place.

The court of appeals held that these findings, coupled with the district court's other findings, namely, that the physicians' initial skepticism was quickly being overcome and that the percutaneous technique was rapidly becoming "the method of choice" (P. 22a, P. 32a), undermined and rendered clearly erroneous the inference drawn by the district court that Datascope would not have garnered these early SMEC sales.

We use the term "inference" rather than "finding" because that which the court of appeals held to be clearly erroneous was not a true finding of fact. Instead, it was an inference or a guess as to what would have happened in some hypothetical situation. The underlying findings of fact were accepted by the court of appeals, only the inference to be drawn from those findings was held to be clearly erroneous. Thus, the court of appeals did not, as petitioner charges, "make its own determinations of disputed facts" (P. 6) and, accordingly, it did not exceed the legitimate scope of appellate review under Rule 52(a).

There is, in addition, an independent ground given by the court of appeals for reversing the district court and awarding lost profits to Datascope — a ground not even addressed in the petition, and one which was decided by the court as a matter of law. As noted above, the court of appeals accepted the district court's finding that at some point in time even SMEC's most loyal and devoted customers would have switched, whether or not SMEC entered the market. The issue was not, therefore, "whether" that would have happened, but, rather, "when". Obviously, however, no one can answer that question with any degree of certainty. As the court of appeals noted, therefore, this circumstance alone warrants awarding lost profits to Datascope (P. 11a, n.6). As a matter of law, when there is such uncertainty — and it can scarcely be doubted that uncertainty exists here — the risk which necessarily accompanies uncertainty must be borne by the wrongdoer/infringer, not by the injured patentee. *Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 563

(1931); *Kori Corp. v. Wilco Marsh Buggies & Draglines, Inc.*, 761 F.2d 649, 655 (Fed. Cir.), *cert. denied*, 474 U.S. 902 (1985). Here, the only way to assure compliance with this mandate is to award lost profits to Datascope even on SMEC's earliest sales.

2. *Willfulness*

On this issue, as well, the court of appeals accepted the basic findings of fact made by the district court. That which was reversed for being clearly erroneous, was the inference drawn by the district court, not the court's own basic findings of fact themselves. As an alternative ground, the court also reversed because the linchpin of the district court's ultimate determination, namely, the opinion of counsel, was grossly inadequate as a matter of law.

In referring to the proper inference to be drawn from the underlying facts, the court of appeals specifically referred to the district "court's own findings about the market pressure and urgency faced by SMEC." (P. 15a). Among those findings are the following:

1. Datascope introduced the percutaneous IAB in late 1979 (App. 6).

2. For about a year and a half, Datascope had the only percutaneous IAB on the market (P. 22a, 24a, App. 6).

3. "SMEC lost customers during the period that Datascope was the only company on the market with a percutaneous balloon." (P. 31a).

4. There was " a certain urgency on SMEC's part prior to entering the percutaneous market." (P. 31a).

5. The urgency on SMEC's part was so great that even a 19 day delay was unacceptable (P. 31a).

6. "Schiff [SMEC's President] considered Datascope's introduction of a percutaneous balloon to be a significant development in the market." (P. 30a).

7. "Despite . . . early doubts within the medical community, the [percutaneous] method was rapidly accepted within a year to a year and a half." (P. 32a).

8. "[T]he relatively prompt acceptance of the technology was not lost upon Schiff and SMEC." (P. 32a).

9. Mr. Schiff first conceived the infringing design, tried to avoid infringement by developing a non-twisting design, was unsuccessful in that effort, and only then returned to the infringing design because it was "the only practical device available" to him (P. 30a).[4]

None of these underlying findings of fact was disturbed on appeal. Contrary to petitioner's assertions, the court of appeals did not replace "the findings of the District Court with those of its own." (P. 8). Instead, it entered judgment based upon the district court's own findings.

As alluded to earlier, in deciding that the infringement was not willful, the district court relied exclusively upon the existence of an opinion of counsel, an opinion allegedly to the effect that the patent was invalid and not infringed (P. 33a-34a). The court of appeals, however, found counsel's opinion, as a matter of law, to be inadequate. First, the court of appeals pointed out that contrary to the statement of the district court (P. 33a), counsel's opinion made no mention whatever of validity. Second, as to infringement, it was merely conclusory. In addition, it "ignores entirely the question of infringement under the doctrine of equivalents" (P. 15a). As the court of appeals noted, because the prosecution history of the patent in suit had never even been ordered, much less consulted, "an opinion on equivalents in this case *would have been impossible*." (emphasis supplied) (P. 15a).

Since the opinion, as a matter of law, was inadequate, it necessarily follows that SMEC cannot point to reliance thereon as justification for its acts. And, once the opinion and alleged reliance thereon are discarded, there no longer exists any basis whatsoever for the district court's determination that the infringement was not willful. To the contrary, we are then left with the findings enumerated above which leave no doubt that the infringement was knowing, deliberate and willful.

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[4] The evidence of record fully supports these findings and demonstrates that SMEC went forward with full knowledge that its activities would likely be deemed to infringe. (P. 16a).

RULE 52(a) DOES NOT NECESSARILY REQUIRE A REMAND TO THE DISTRICT COURT

Although, as demonstrated above, the court of appeals did not substitute its own findings for those of the district court, even if it had, that is not necessarily impermissible.

> Although reversal of a trial court finding of fact as clearly erroneous generally requires a remand to the district court for further proceedings, *see Pullman-Standard v. Swint*, 456 U.S. 273, 291-92, 102 S.Ct. 1781, 1791-92, 72 L.Ed.2d 66 (1982), the reviewing court may make the appropriate finding in the first instance where the record permits only one resolution of the factual issue.

LaRoche v. United States, 779 F.2d 1372, 1377 (8th Cir. 1985).

> The usual procedure when findings are infirm because of an erroneous view of the law is to remand for further proceedings, but such proceedings are not required when the record permits only one resolution of the factual issue. *Pullman-Standard v. Swint*, 456 U.S. 273, 292, 102 S.Ct. 1781, 1792, 72 L.Ed.2d 66, 82 (1982).

In re Southern States Motor Inns, Inc., 709 F.2d 647, 653 n. 11 (11th Cir. 1983), *cert. denied*, 465 U.S. 1022 (1984).

> However, where a thorough review of the record permits only one resolution of the factual issue - *i.e.*, where any other resolution by the district court would be clearly erroneous - the appellate court may make the appropriate finding in the first instance.

Patterson v. Greenwood School Dist. 50, 696 F.2d 293, 295 (4th Cir. 1982).

Thus, even if petitioner were correct that the court of appeals entered its own findings, that does not establish a failure to abide

by the dictates of Rule 52(a). If, as here, the district court's other findings and the record establish that no findings other than those entered by the court of appeals could be sustained, entry of those findings is proper and remand is not necessary.

In this case, when the court of appeals said that its

> [r]eview of the record creates in us the "definite and firm conviction" of mistake in the district court's finding of "honest doubt . . . as to the validity and infringement of Datascope's patents" (P.15a).

it was in essence saying that any determination other than that the infringement was willful, would necessarily be clearly erroneous. Hence, entry of judgment that the infringement was willful did not require remand.

Similarly, when the court of appeals said

> [o]ur review of the record related to the finding that Datascope failed to carry its burden of proof of entitlement to lost profits on domestic sales under the *Panduit* test leads us inexorably to the 'definite and firm conviction that a mistake has been committed' (P. 11a).

it again was saying that no other outcome would be permissible.

THERE IS NO CALL FOR THIS COURT TO EXERCISE ITS SUPERVISORY AUTHORITY

As demonstrated above, the court of appeals has not, in this case, been guilty of any of the sins with which it has been charged. Since the court of appeals has done nothing improper, there is nothing for this Court to correct and, accordingly, no reason for this Court to exercise its supervisory authority. In addition, petitioner has failed to show any policy consideration to justify intervention by this Court. The questions at issue in the

courts below were between the two litigants and have no widespread policy implications.

Although petitioner seeks to portray the Court of Appeals for the Federal Circuit as a court run amuck, they cite no support for that portrait. Certainly a single, four year old article[5] by two disgruntled authors is a weak reed to rely upon. Moreover, the decisions of the Federal Circuit discussed in the Filardi and Scheinfeld paper cited by petitioner, rather than showing a disregard of Rule 52(a), reflect the Federal Circuit's scrupulous adherence to it. They also reflect a recognition by that court of the difference between errors of law and errors of fact. Only the latter are subject to the clearly erroneous standard. Most of the cases discussed in the Filardi and Scheinfeld article, however, involved errors of law.

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[5] Filardi & Scheinfeld, *Appellate Review of Patent Bench Trials: Is The CAFC Following Rule 52(a)?*, CURRENT DEVELOPMENTS IN PATENT LAW 1985 (1985), *see* (P. 14).

CONCLUSION

The decision of the court of appeals is in full compliance with Rule 52(a) and the cases applying that rule. Each finding and inference of the district court which was reversed, was first found to be "clearly erroneous," as required by Rule 52(a). No *de novo* findings were made, but instead, judgment was entered on those of the district court's own findings which were not held to be erroneous. Finally, to the extent it be deemed that the court of appeals entered judgment on its own findings, it did so because those findings are the only ones which would not be clearly erroneous in view of the instant record and the district court's other findings.

The petition of SMEC should, therefore, be denied and no writ of certiorari issued.

Respectfully submitted,

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APPENDIX

DATASCOPE CORP., Plaintiff,

V.

SMEC, INC., Defendant.

Civ. A. No. 81-3948.

United States District Court,
D. New Jersey.

Sept. 24, 1984.

Greenberg, Dauber & Epstein by Melvin Greenberg, Newark, N.J., Fitzpatrick, Cella, Harper & Scinto by Stevan J. Bosses, New York City, for plaintiff.

Ezra Sutton, P.A. by Ezra Sutton, Woodbridge, N.J., Glosser and Greenburg by Peter A. Greenburg, Washington, D.C., for defendant.

OPINION

CLARKSON S. FISHER, Chief Judge.

This is a suit by Datascope Corporation alleging infringement by SMEC, Inc., of claims 1 through 8, 18, 19, 21, 22, 24, 25, 26 and 27 of United States Letters Patent No. 4,261,339 ('339 patent) and claims 1 through 3 and 9 through 15 of United States Letters Patent No. 4,327,709 ('709 patent). Defendant has denied infringement and alleges that the '339 patent is invalid due to anticipation (35 U.S.C. §102), and that both patents are invalid due to obviousness (35 U.S.C. §103). The following constitute my findings of fact and conclusions of law as mandated by Fed.R.Civ.P. 52(a).[1]

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[1] At the request of the parties, the court has bifurcated the hearing of this case. Trial of the issues of monetary damages, whether an injunction should issue in the event that infringement is established, and the issues raised by SMEC's counterclaims relating to alleged violations of the antitrust laws and unfair competition have been deferred. The case thus far has been tried solely on the issues of validity and infringement of the '339 and '709 patents.

I. *Background*

In about 1966 a device called the intra-aortic balloon catheter (IAB) was first conceived and fabricated. Credit for that development is generally given to Dr. Adrian Kantrowitz who was, at the time, on the staff of Maimonides Hospital in Brooklyn, New York. Working with Dr. Kantrowitz on that invention was Mr. Sidney Wolvek, one of the inventors of the two patents here in suit.

An IAB consists primarily of two segments: the balloon chamber, often referred to simply as the balloon, and the catheter tube portion. The catheter tube portion is a long thin hollow plastic flexible tube, one end of which is fed into an artery and the other end of which remains outside the body. The balloon, which is sausage shaped, is attached to the far (distal) end of the catheter tube, the end that goes into the body. The near (proximal) end of the catheter tube, the end that remains outside the body, is equipped for connection to an external pump console. The console pumps gas, usually helium or carbon dioxide, through the catheter tube into the balloon chamber. The catheter tube portion and balloon together are about 30 to 36 inches long, with the balloon itself being about ten inches long.

Unlike a child's latex toy balloon, the balloon of an IAB is not distensible, i.e., does not stretch. Rather, it is more like a paper bag which can be inflated and deflated but which has a constant surface area irrespective of whether it is in its inflated or collapsed state. Thus, within certain tolerance limits, the maximum size of the IAB balloon chamber is predetermined and is not a function of inflation pressure, unlike a latex balloon which increases in volume as the gas pressure builds.

In use, the balloon portion of the device is maneuvered by a physician so that it is in the descending aorta, the major artery leading from the left ventricle of the heart to the other organs of the body. The balloon is then inflated and deflated again and again, out of phase with the natural pumping action of the heart. In other words, immediately after the heart relaxes following a pump cycle, the balloon is inflated and just before the heart begins the next pumping action the balloon is deflated. This process is often called "counterpulsation."

The timing of the inflate/deflate cycle is controlled by the patient's electro-cardiogram or aortic blood pressure so that it is properly synchronized to the patient's natural heart rhythm. When the balloon is inflated, it necessarily forces blood out of the portion of the aorta where the balloon is located. In so doing, the inflation of the balloon causes a second pumping action, supplementing the natural pumping action of the heart. In particular, it forces extra oxygen-containing blood through the coronary arteries, thereby providing additional nourishment to the heart. Thereafter, when the balloon is deflated, the pressure in the aorta is lowered. Since there is then much less back pressure against which the heart must work, the exertion of the heart muscle during the next pumping cycle is substantially reduced.

The IAB is a temporary assist device, typically being left in the patient for about three days. It is frequently used after open-heart surgery to help wean a patient off the heart-lung machine. In addition, however, it is often used for patients suffering from cardiogenic shock, myocardial infarction and acute angina pectoris and is frequently used also to sustain patients who might not otherwise be able to sustain themselves until permanent treatment can be effected.

When in use, i.e., during counterpulsation, the balloon portion of the IAB is located in the descending aorta leading from the heart. It is normally inserted into the body, however, through the femoral artery, which is located in the groin area of the thigh. From there, by pushing on the catheter tube itself, the physician can feed the balloon up through the arterial system until it reaches the aorta.

Prior to the embodiment of the '339 patent, all IAB's had to be inserted by a surgeon. The surgical procedure, which is still preferred by some physicians, requires extensive general or local anesthesia and takes about 45 minutes. The femoral artery must be exposed by making an incision in the groin. A second incision must then be made in the artery, a graft must be sewn in and the IAB inserted. Removal of the device requires surgery as well.

With FDA clearance on October 1, 1979, of plaintiff's IAB, which later received patent number '339, it became possible for the first time to insert an IAB by puncturing the artery with a needle instead of using surgery. This procedure is called percutaneous insertion, and its use with other types of catheters has been known by physicians and others in the medical field since 1952 or earlier. *See* Seldinger, *Catheter replacement of the needle in percutaneous arteriography*, Acta Radiol (Stockholm, Sweden), 39:368 (1953).

In percutaneous insertion, the patient is given a local anesthetic, after which a small incision is made in the skin over the femoral artery. A hypodermic needle somewhat larger than those in common use is then used to puncture the femoral artery. The needle is replaced by a guide wire, over which is inserted a sheath. The IAB is introduced into the artery through the sheath. Percutaneous insertion of an IAB can be accomplished in under five minutes without the physical trauma generally associated with surgery.

II. *Description of the Patents in Suit*

A. '339 Patent

On April 14, 1981, the '339 patent was issued to plaintiff as assignee of two of its employees, Bruce L. Hanson and Sidney Wolvek, for an invention entitled "Balloon Catheter with Rotatable Support." The inventors had filed their application for a patent on March 6, 1978. The '339 patent is directed to an IAB which is so constructed as to permit reducing the cross-sectional diameter of its balloon section, when prepared for insertion in the body, to a size no larger than the diameter of the catheter tube to which it is attached.

In the prior-art surgical balloons in use at the time of the invention,[2] the catheter tube itself ran the entire length of the

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[2] Defendant alleges that the '339 patent is anticipated by the Grayzel reference, U.S. patent 3,939,820, which apparently has never been commercialized. This contention will be addressed below, and the present discussion will be confined to prior-art IAB's which have been in actual use.

balloon. In other words, the far (distal) end of the balloon was cemented to the far end of the catheter tube and the near (proximal) end of the balloon was also cemented to the catheter tube about six or eight inches back from its end. Gas entered the balloon chamber through holes punched in that portion of the catheter tube enclosed within the balloon. In addition to serving as a conduit for the gas, the catheter tube within the balloon chamber served as a support member. Without a support the balloon would be flaccid and would simply fold back over the tube during insertion. Once folded back in this fashion it would be virtually impossible to inflate or deflate.

From the very outset of balloon pumping in the 1960's, it was recognized that the smaller the size or profile of the device as it was being inserted into the femoral artery and being fed up into the aorta, the better. Making this entering profile small, however, has always presented difficulties because the balloon membrane does not contract when deflated. This problem is not encountered when using other kinds of catheters that employ latex or stretchable balloons. Those balloons, when deflated, contract naturally until they hug the catheter tube tightly.

Since the membrane of an intra-aortic balloon does not contract, some other method must be employed to make the entering profile as small as possible. With the prior-art surgical IAB, this was accomplished by bunching or wrapping the balloon membrane around the catheter tube within it. Because the catheter tube was within the balloon, however, no matter how tightly bunched the balloon could not be made any smaller than the tube itself. Indeed, when wrapped around the tube, the balloon had necessarily to be considerably larger in diameter than the tube itself.

In order to reduce the profile of the wrapped balloon, Messrs. Hanson and Wolvek, instead of attaching both ends of the sausage-shaped balloon to the tube, decided to attach only the proximal end of the balloon to it. Then, in order to provide support for the balloon membrane and prevent it from folding back on itself or on the catheter tube, they ran a very thin stainless

steel wire from the end of the tube through the balloon to its tip. Because the wire is much thinner than the catheter tube when the balloon is wrapped about the wire, it can be made to have a diameter at least as small as that of the tube. Since the physician guides the balloon up to the aorta by pushing on the catheter tube, a means of preventing the support wire from sliding or telescoping into the catheter tube was added, thereby insuring that the pushing force is transmitted from the tube to the support wire to the balloon tip.

In addition, the '339 patent calls for the support member to be rotatable either at the balloon tip or at the catheter tube so that one end of the balloon can be twisted relative to the other. By permitting the support member to rotate, it is possible to twist the balloon into a very tight spiral wrap about the support wire. "Rotate," in this context, means being able to twist the balloon membrane tightly about the support member without inducing torsional stresses to the catheter tube which would tend to damage or distort the tube.

The claims are not directed to a method of percutaneous insertion of an intra-aortic balloon catheter, but only to the structure of a balloon catheter which may be inserted in any way, either surgically or percutaneously. Nevertheless, due to the structure of the patented device, it has been recognized since the first commercial embodiment went on the market in 1979 that the significance of the '339 patent lies in the feasibility of inserting an IAB percutaneously.

B. '709 Patent

On May 4, 1982, the '709 patent was issued to plaintiff as assignee of the same two inventors for their invention entitled "Apparatus and Method for the Percutaneous Introduction of Intra-Aortic Balloons into the Human Body." The application for the '709 patent was filed on October 18, 1979, and was a continuation-in-part of the application which eventually became the '339 patent.

The '709 patent is directed to a system which can be used to achieve percutaneous insertion of an IAB into an artery. The patent also contains claims to the process for accomplishing such insertion. Only the system claims are alleged to have been infringed.

The system includes a sheath adapted for insertion into an artery through a puncture and a balloon catheter comprising a catheter tube, a balloon envelope having one end connected to one end of the catheter tube and an elongated flexible support member within the balloon envelope coupled to the ends of the balloon envelope so that the balloon will fold generally longitudinally along the axis of the support member to reduce the diameter sufficiently that the device may be inserted through the sheath into an artery.

The balloon catheter described in the '709 patent is substantially similar to the preferred embodiment of the '339 patent except that the support member is *not* rotatable. According to the specification of the '709 patent, the twisting or winding of the balloon around the support member "give rise to the formation of oblique wrinkles on the wrapped profile exposing the interior walls of the artery to said wrinkles thereby making it somewhat more difficult to insert the balloon and dependent on complete unwrapping to achieve efficacy." Thus, in the system taught by the '709 patent, "there is no twisting or wrapping of the envelope to present convoluted surfaces to the artery." Instead, a vacuum is applied to the interior of the balloon via the catheter tube, which causes the balloon to collapse and fold longitudinally about the support member as the device is pushed through the sheath. Sidney Wolvek, one of the inventors, testified that he was not aware of any instance in which the system and method taught by the '709 patent was put into use.

III. *Description of the SMEC IAB*

The SMEC device alleged to infringe the '339 patent includes a balloon, a catheter tube connected to the proximal end of the balloon, and a wire, or stylet, fixedly connected to the distal end

of the balloon with the stylet extending throughout the length of the balloon, through the full length of the catheter tube, and through a Y-connector at the proximal end of the catheter tube. The proximal end of the stylet is connected to a brass screw which is connected to a knob at the proximal end of the catheter tube, which constitutes a wind-up mechanism used to twist the balloon and wrap it about the stylet. The wind-up mechanism is also used to unwrap the balloon once it is in place in the aorta and to re-wrap it to facilitate withdrawal after counterpulsation has been accomplished.

The SMEC percutaneous IAB is sold as part of a system. Among the other elements of the system are a sheath, a dilator with a tapered end over which the sheath fits, a guide wire that fits through a bore in the dilator, and a hollow angiographic needle through which the guide wire can pass.

IV. *Validity*

The two patents in suit enjoy a statutory presumption of validity. 35 U.S.C. §282. The burden of overcoming that presumption and proving invalidity is on the defendant, SMEC, Inc., and it must do so by clear and convincing evidence. *American Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1360 (Fed.Cir. 1984). The production of new prior art not before the Patent and Trademark Office (PTO) eliminates or reduces the deference due the PTO as a qualified government agency presumed to have properly done its job, but it does not shift or change the burden of proof. *Id.* at 1359-60.

A. Anticipation

A patent is invalid if "anticipated" by a prior-art reference. 35 U.S.C. §102. Anticipation requires that each element of the claimed invention be disclosed in a single prior art reference. *Lindemann Maschinenfabrik v. Amer. Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

SMEC alleges that the '339 patent is anticipated by Grayzel, U.S. patent 3,939,820. Grayzel discloses an IAB with virtually

all the elements of the '339 patent. It is the element of rotatability of the support member which is in doubt and which defendant has attempted to demonstrate is disclosed in Fig. 2 of Grayzel.

Since Grayzel appears never to have been commercialized, and neither the specification nor the claims of Grayzel make any reference to rotatability, defendant's charge of anticipation stands or falls on this court's determination of whether the junction between two elements in Fig. 2 of Grayzel would represent a ball and socket joint to a person of ordinary skill in the art. If so, the support member in Grayzel would be able to rotate, and the '339 patent would be anticipated by this reference.

Defendant has failed to discharge its burden of proving anticipation. Defendant's expert witness, Mr. Marzullo, admitted at his deposition that if a ball and socket were meant to be represented by Fig. 2 of Grayzel, they were improperly drawn. His attempt to recant this testimony at trial only served to damage his credibility.

Furthermore, if Grayzel had intended to disclose a rotatable support member, one would have expected express reference to such a feature, as it would have represented a significant departure from the prior art. Anticipation cannot be predicated on teachings in a reference that are vague or based on conjecture. *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1554 (Fed. Cir. 1983). Accordingly, I find that the '339 patent is not anticipated by Grayzel.

B. *Obviousness*

In determining whether an invention is obvious within the meaning of 35 U.S.C. §103, a court must (1) determine the scope and content of the prior art, (2) ascertain the differences between the prior art and the claims of the patent in issue, and (3) determine the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 86 S.Ct. 684, 693, 15 L.Ed.2d 545 (1966). Such secondary considerations as commercial success, long-felt but unsolved need, and failure of others may also be relevant to the court's inquiry, *id.* at 17-18, 86 S.Ct. at 693-694,

and must be considered when present. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983).

1. '339 *Patent*

"The scope of the prior art has been defined as that 'reasonably pertinent to the particular problem with which the inventor was involved.' . . ." *Stratoflex*, 713 F.2d at 1535 (citations omitted). The problem confronting Hanson and Wolvek, inventors of the '339 patent, was how to reduce the cross-sectional diameter of the balloon chamber of an IAB to facilitate its insertion into the body.

Among the references the patent examiner considered were Fettel, Tower and British patent 512,456. While these references cannot be said to be totally irrelevant, the balloon portion of the device is made of latex, which contracts when deflated to hug the catheter tube tightly. Fogarty, which was not before the examiner, is the same type of device. Thus, a solution to the problem of how to wrap the balloon chamber of an IAB in order to reduce its size is not likely to have been suggested by a reference in which the size of the balloon is not in issue.

Testimony by defendant's expert that a non-distensible balloon could be substituted for the distensible one taught in the above reference is not persuasive. The fact that the prior art could be modified would not have made the modification obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984). Since the use of a non-distensible balloon in a device employing a distensible one would create the problem of reducing the size of the balloon and would not solve any problem, the latex balloon references teach away from the modification proposed by SMEC.

Moulopoulos, a reference that was not before the patent examiner, discloses an artificial heart valve comprised, in part, of a flexible membrane in the form of an umbrella which, when collapsed, folds about an axis. Moulopoulos is unusual in that it contains seven figures, only three of which are discussed in the text. SMEC relies on Figs. 3, 4A, 4B and 5, which are among

those not mentioned. I find that these figures do not, in themselves, teach or suggest rotatability. Furthermore, as defendant's patent expert, Mr. Marzullo, admitted, Moulopoulos is almost identical to Leininger which was before the patent examiner along with more pertinent references such as Grayzel and the original IAB invented by Dr. Kantrowitz.

SMEC introduced testimony to the effect that the Kantrowitz reference in which the catheter tube does not occupy the balloon chamber but is replaced by a flexible wire braid of the same diameter as the tube, teaches rotatability. In his deposition, Dr. Kantrowitz testified that the braid in his IAB, which is no longer in use, was capable of being twisted one or two turns and was so twisted in actual practice to facilitate wrapping of the balloon prior to surgical insertion. Kantrowitz went on to point out, however, that twisting the braid more than two rotations would tend to damage and eventually destroy it. Thus Kantrowitz could not be said to be rotatable in the sense that term was employed by Hanson and Wolvek to describe their invention. It is a well-established principle of patent law that a patentee is entitled to be his own lexicographer and is not limited to dictionary meanings of the words he uses to describe his invention. *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1569 (Fed. Cir. 1983).

As I have already indicated, Grayzel does not disclose a rotatable structure. There is, thus, no prior art reference that teaches this critical element of the '339 patent, so that no combination of references could suggest and thereby render obvious the inventors' idea of constructing an IAB with a thin support member that rotates to allow one end of the balloon to twist relative to the other.

Testimony by experts on both sides that they first greeted the news of Hanson and Wolvek's invention with skepticism is highly probative evidence of non-obviousness. *Environmental Designs v. Union Oil Co.*, 713 F.2d 693, 697 (Fed. Cir. 1983), *cert. denied*, ____ U.S. ____, 104 S.Ct. 709, 79 L.Ed.2d 173 (1984). Particularly persuasive here was the testimony of Adrian Kantrowitz, who, as inventor of the first IAB, possesses at least ordinary skill in

the art. The secondary considerations of long-felt but unsolved need and the great commercial success of the invention[3] also support a finding of non-obviousness.

a. Texas Incident[4]

Defendant elicited testimony from two Texas surgeons who in the early 1970's, upon experiencing difficulty with SMEC surgical IAB's breaking, noticed that the broken catheter tube could be twisted to allow the balloon to be wrapped tightly around it. One of the doctors testified that he brought this discovery to the attention of Peter Schiff, president of SMEC and inventor of the device alleged to infringe the patents in suit.

A drawing of the broken catheter made to represent those made at the time to illustrate the doctors' discovery has been admitted into evidence, and it shows the catheter tube extending the full length of the balloon chamber. Thus, even if the tube were twisted, the diameter of the balloon chamber would still exceed that of the catheter tube. Furthermore, there is no evidence that Schiff took any steps at the time to design an IAB that incorporated the doctors' suggestions. Rather, the evidence indicates that he viewed the breaking of the tubes as a problem and sought to correct it. Since both sides agree that Mr. Schiff is a person of ordinary skill in the pertinent art, his failure to perceive the supposed significance of the discovery and to capitalize on it is more indicative of non-obviousness than of obviousness. Accordingly, I find the '339 patent not obvious within the meaning of section 103.

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[3] By conservative estimate, at least 70% of all IAB's sold today are designed and intended for percutaneous insertion.

[4] Although this evidence might appear to have been introduced by SMEC to support an assertion that the '339 patent is anticipated by a prior invention pursuant to § 102(g), such an assertion has not been made and would be unmeritorious in any event. *See Lockheed Aircraft Corp. v. United States*, 553 F.2d 69, 75 (Ct. Cl. 1977). Rather, defendant seems to have attempted to demonstrate obviousness under section 103, which is the framework in which I have evaluated the evidence.

2. *'709 Patent*

Because the application which eventually became the '709 patent was a continuation-in-part of the application for the invention described in the '339 patent, the '339 patent is not prior art as to the '709 patent. Thus, the teachings of the '339 patent must be disregarded in determining whether the '709 patent is invalid due to obviousness.

The parties have agreed as to the level of ordinary skill in the relevant art, both sides having called as witnesses individuals without advanced degrees in engineering but with many years of experience designing medical devices of the type here in suit. I find that the most pertinent prior art was before the examiner but that, nevertheless, the system and process for percutaneous insertion of an IAB disclosed in the '709 patent would have been obvious to someone possessing ordinary skill in the art at the time of the invention.

The Grayzel reference discloses every element of the IAB described in claim one of the '709 patent. Since rotatability is not a feature of the IAB utilized in the '709 system (in fact, the specification indicates that twisting of the balloon is disadvantageous and is avoided by the '709 patent), Grayzel is relevant to a consideration of obviousness here for the same reason it was not particularly relevant to obviousness with respect to the '339 patent.

As the patent specification itself notes, moreover, the technique of percutaneously inserting a catheter through a sheath or cannula had been described in the medical literature many years earlier. Secondary considerations support a finding of invalidity, since the patent has never been commercialized. Accordingly, I find that the '709 patent is invalid under section 103.

V. *Infringement*

A. '339 Patent

SMEC has bottomed its non-infringement defense primarily on two differences between the patented device and SMEC's allegedly infringing product. First, defendant claims that its support member or stylet is not rotatably "coupled" to the catheter tube but passes freely through it. Second, the stylet in the SMEC device does not terminate somewhere within the catheter tube but extends all the way through the tube, terminating at the proximal end, where it is connected to a knob by which it is twisted to wrap the balloon.

According to Mr. Wolvek, who is a person of ordinary skill in the art, the word "coupled," as he used it in the '339 patent, means "that the two items are placed together in a cooperative manner so that one cooperates with the other." SMEC has accepted this definition of coupled, but its technical expert has testified that no such cooperation exists between the stylet and the catheter tube in the SMEC device. I find such testimony unpersuasive.

In order for the winding mechanism at the end of the catheter tube to rotate the stylet lying inside the tube, there must be some cooperation between those two elements. Defendant, in fact, sought to prove at trial that the SMEC device uses the catheter tube to transmit torque from the stylet to the balloon in order to wrap it.[5] I find that a coupling like that described in the '339 patent exists between the stylet and the catheter tube in the SMEC device.

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[5] This argument was advanced to distinguish the SMEC device from the '339 patent on the basis of a statement in the specification to the effect that the torque applied to twist the balloon is not imparted to the catheter tube. This statement, however, cannot be read so literally as to assume that no torque whatsoever will be imparted, but rather only that transmission of an amount sufficient to damage the tube is avoided. In this respect, the SMEC device does not differ from the patented device.

Not all infringements are literal, however, and as the Supreme Court has recognized, "to permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing." *Graver Tank & Mfg. Co. v. Linde Air Products*, 339 U.S. 605, 607, 70 S.Ct. 854, 856, 94 L.Ed. 1097 (1950). The doctrine of equivalents evolved to address this problem. Simply stated, the doctrine allows the patentee to charge with infringement the producer of a device that performs substantially the same function in substantially the same way to obtain the same result as that called for by the patent. *Graver Tank*, 339 U.S. at 608, 70 S.Ct. at 856.

The doctrine of equivalents is circumscribed in certain circumstances by another doctrine – that of file wrapper or prosecution history estoppel. This doctrine precludes a patent owner from obtaining a claim construction that would resurrect subject matter surrendered during prosecution of the patent. *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1362 (Fed. Cir. 1983). "The estoppel applies to claim amendments to overcome rejections based on prior art, . . . and to arguments submitted to obtain the patent. . . ." *Id.* (citations omitted).

Defendant has asserted that those claims of the patent which call for the coupling to occur at or adjacent the proximal end to the balloon chamber are not literally infringed by the SMEC device, and that plaintiff is estopped to invoke the doctrine of equivalents due to amendments of the patent application to overcome prior-art rejections. Defendant has failed to adduce evidence of my rejection whatsoever based on the *location* of the coupling, however.

As to the length of the support member, the patent clearly indicates that it extends from the distal tip of the balloon to a point in the catheter tube adjacent to the balloon chamber. There is, thus, no literal infringement with respect to this limitation. Once again, however, the doctrine of equivalents may be invoked to find infringement.

SMEC's long stylet and wind-up mechanism twist the balloon into a tight spiral to allow for percutaneous insertion into the artery in substantially the same manner taught by the '339 patent. The only real difference is that in using the patented device, one grasps the distal end of the balloon and rotates the support member by hand instead of turning a knob at the opposite end of the catheter tube. That defendant's wind-up mechanism may represent an improvement over the patented device does not avoid infringement, however. *Lockheed*, 553 F.2d at 83.

SMEC seeks to limit plaintiff's resort to the doctrine of equivalents by an estoppel based on the fact that certain prior art references show support members running the full length of the catheter tube. But defendant has failed to make the necessary causal connection between plaintiff's amendments to its patent application and this particular feature of the prior art. Defendant's patent expert, Mr. Marzullo, admitted that the file wrapper contains no reference to the length of the support member in its discussions of patentability over the prior art. Accordingly, I find that plaintiff has met its burden of proving by a preponderance of the evidence that the '339 patent claims in suit are infringed by the SMEC device.

B. '709 Patent

I have concluded that the '709 patent is invalid, but in the event this holding is overturned on appeal, I find that the system claims of the '709 patent are infringed by defendant's combination IAB and system for percutaneous insertion. Although defendant's IAB is not intended to be used in the manner taught by the process claims of the patent (i.e., the SMEC device is to be twisted prior to insertion) those claims are not alleged to be infringed.

Defendant need only make, use or sell the components of its system, each of which reads on an element of the '709 patent, to infringe the system claims of that patent. Accordingly, I find that plaintiff has proven infringement by SMEC of the system claims of the '709 patent.

VI. *Conclusion*

All claims of the '339 patent are valid, and claims 1 through 8, 18, 19, 21, 22, 24, 25, 26 and 27 are infringed. All claims of the '709 patent are invalid, and claims 1 through 3 and 9 through 15 are infringed. Plaintiff will submit an order within 5 days.